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**UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

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*Ex parte* ANTHONY TORANTO, EVAN SINGER and  
BRETT MILLER

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Appeal 2007-2708  
Application 09/976,872  
Technology Center 1600

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Decided: December 21, 2007

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Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and  
FRANCISCO C. PRATS, *Administrative Patent Judges*.

PRATS, *Administrative Patent Judge*.

**DECISION ON APPEAL**

This is an appeal under 35 U.S.C. § 134 involving claims to a method for detecting the presence of an analyte in saliva. The Examiner has rejected the claims as anticipated and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

**STATEMENT OF THE CASE**

***THE INVENTION***

“The present invention relates to analyte detection test systems, including test systems for the oral detection of analytes in saliva” (Spec. 1).

Using the disclosed methods, substances including metabolites, illicit drugs, disease causing agents, and compounds indicative of the presence of disease can be detected in the saliva (*see id.* at 4).

Claims 1-15 and 18-27 are pending and on appeal (App. Br. 3).<sup>1</sup>

Claim 1 is representative and reads as follows:

1. A method for detecting the presence of an analyte in saliva, comprising:
  - a) providing an assay test comprising a reaction site that produces a detectable signal in presence of an analyte; wherein said reaction site comprises a non-toxic chromogen;
  - b) placing said reaction site into a mouth of a subject under conditions such that saliva from said subject is contacted with said reaction site; and
  - c) detecting the presence or absence of said detectable signal in said reaction site.

### *THE REJECTIONS*

The Examiner applies the following documents in rejecting the claims:

Manautou	US 3,875,013	Apr. 1, 1975
Kindler	US 5,494,831	Feb. 27, 1996
Bogema	US 6,248,598 B1	Jun. 19, 2001

The following rejections are before us for review:

Claims 1-4 and 11 stand rejected under 35 U.S.C. § 102(b) as anticipated by Manautou (Ans. 3).

Claims 5, 6, 8-15, and 18-27 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Manautou and Bogema (Ans. 3-5).

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<sup>1</sup> Appeal Brief filed September 24, 2004.

Claim 7 stands rejected under 35 U.S.C. § 103(a) as obvious in view of Manautou and Kindler (Ans. 5).

## THE ANTICIPATION REJECTION

### *ISSUE*

The Examiner cites Manautou as describing “a test that provides for detecting the fertile period or the presence of pregnancy in a female. In one embodiment, the saliva of a female is tested orally, in which her tongue wets the test paper and waits about 20 minutes before forming a color” (Ans. 3). The Examiner states that “[t]he test strips are impregnated with reagents for the practice of the invention as recited in claims 1-6,” and that “[t]he test strips [are] then compared to a standard color card that has a series of color spots similarly developed from known concentrations of the color compound p-nitrophenol (chromogen) as recited in claims 2, and 11” (*id.* (citations omitted)).

Appellants contend that Manautou “contains no teaching of the use of a non-toxic chromogen, which is a novel and essential element of the presently claimed invention. Rather, Manautou *et al.* teaches the use of p-nitrophenol, a compound known for its high toxicity” (App. Br. 17).

The Examiner responds that “certain levels of any chemical can be toxic,” and that the amount of p-nitrophenol used in Manautou’s assay was small enough to be considered non-toxic (Ans. 6-7).

The issue with respect to this rejection, therefore, is whether the Examiner erred in finding that Manautou describes a method for detecting an analyte in saliva, wherein the assay’s “reaction site comprises a non-toxic chromogen” as recited in claim 1.

*FINDINGS OF FACT*

1. Claim 1 recites a method of detecting an analyte in saliva. The detection method is performed by (a) providing “an assay test” that has a reaction site that produces a detectable signal in the presence of the analyte, (b) placing the reaction site into a subject’s mouth in a manner that causes saliva from the subject to be contacted with the reaction site, and (c) detecting the presence or absence of the detectable signal in the reaction site.
2. Manautou describes a “test method suitable for detecting the . . . fertile period [of a female] or the presence of pregnancy” (Manautou, col. 1, ll. 7-9). For example, Manautou discloses that the activity of the enzyme N-acetyl- $\beta$ -glucosaminidase is increased during certain parts of the menstrual cycle (*id.* at col. 3, l. 59, through, col. 4, l. 2; *see also* Figure 1).
3. In the test method, “[a] typical test paper is prepared for oral use . . . by impregnating [a] porous strip with, for example, 0.1 to 0.5 ml of buffered substrate consisting of 0.1 M p-nitrophenyl-n acetyl - $\beta$ -d-glucosaminide described in 0.1 M sodium citrate buffer” and then dried, leaving the active ingredients on the paper (Manautou, col. 3, ll. 29-38). Manautou discloses that “[i]n the oral test, the female simply touches the test paper to her tongue to wet it and then waits about 20 to 40 minutes, usually 30 minutes, at room temperature for the increase in N-acetyl- $\beta$ -d-glucosaminide to form a color developing compound” (*id.* at col. 3, ll. 41-46). To determine the amount of enzyme activity in the saliva sample, “[t]he test strip is then compared to a standard color card that has a series of color spots similarly developed from known concentrations of the color developing compound p-nitrophenol” (*id.* at col. 3, ll. 48-53).

4. Manautou discloses that “the color developing reagent suitable for the purpose of the present invention is selected from the commercially available compounds p-nitrophenyl-n-acetyl- $\beta$ -d-glucosaminide,  $\alpha$ -naphthol-n-acetyl- $\beta$ -d-glucosaminide, 1-[p-nitrocatechol]-n-acetyl- $\beta$ -d-glucosaminide, 2-[p-nitrocatechol]-n-acetyl- $\beta$ -d-glucosaminide, and 3,3-bis(p-hydroxyphenyl)phthalid-n-acetyl- $\beta$ -d-glucosaminide” (Manautou, col. 2, ll. 53-60).
5. Manautou discloses that 40 female patients participated in a study using the disclosed test to determine the peak of N-acetyl- $\beta$ -glucosaminidase activity and its relationship to pregnancy (Manautou, col. 4, ll. 38-50; *see also* Figure 4).
5. Claim 1 limits the reaction site of the claimed assay to one that “comprises a non-toxic chromogen.”
6. The compound “p-nitrophenyl-n acetyl - $\beta$ -d-glucosaminide,” which is impregnated onto Manautou’s test paper and touched by the test subjects’ tongue, is not disclosed by Manautou as being toxic. Manautou does not disclose that p-nitrophenol, the color developing compound released from p-nitrophenyl-n acetyl - $\beta$ -d-glucosaminide by the enzyme in the test subject’s saliva, is toxic.
7. Appendix B of the Appeal Brief contains a seven page document entitled “NTP Chemical Repository Data Sheet For P-Nitrophenol.”<sup>2</sup> The

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<sup>2</sup> It does not appear that this document has been cited by Appellants on an Information Disclosure Statement (e.g., PTO/SB/08A, 08B, or Form PTO-1449), or by the Examiner on either List of References Cited (*see* Forms PTO-892, December 4, 2002 and November 28, 2003). While the date of the document is not clear, the last page of the document has an entry stating “Last revised: 13 August 2001” (App. Br. Appendix B at 7).

top of each page contains the following entry:

“[http://ntp-support.niehs.nih.gov/NTP\\_Re...m\\_HS\\_HTML/NTP\\_Chem1/Radian100-02-7.html](http://ntp-support.niehs.nih.gov/NTP_Re...m_HS_HTML/NTP_Chem1/Radian100-02-7.html).”

Under the heading “TOXICITY”, the NTP Data Sheet for p-nitrophenol contains an entry stating that the “LD50” in “orl” mode for a rat is 250 mg/kg (App. Br. Appendix B at 2). The NTP Data Sheet contains an LD50 in “orl” mode for a “mam” as 247 mg/kg, and an LD50 in “skn” mode a “mam” as 920 mg/kg (*id.*). We find this to mean that the LD50, or oral dosage that is lethal to 50 percent of test animals, is about 250 milligrams per kilogram of body weight for rats and other mammals.

Under the heading “HANDLING PROCEDURES” the NTP Data Sheet for p-nitrophenol states that “[t]his compound is highly toxic by ingestion, inhalation or absorption through the skin. When heated to decomposition it emits toxic fumes. It is corrosive to the skin” (App. Br. Appendix B at 3).

Under the heading “EMERGENCY PROCEDURES” the NTP Data Sheet states that skin contact, inhalation, and eye contact with p-nitrophenol are all sufficiently serious to warrant prompt medical attention for ingestion (App. Br. Appendix B at 3). Under “EMERGENCY PROCEDURES” for ingestion, the NTP Data Sheet states “DO NOT INDUCE VOMITING. Phenols are very toxic poisons AND corrosive and irritating, so that inducing vomiting may make medical problems worse” (*id.* at 4).

8. The Specification does not define the term “non-toxic chromogen.” However, the Specification does state:

If no undesired toxic responses are observed when the chromogen is used at a functional (e.g., colorimetric)

concentration, when exposed to the subject in a manner consistent with the methods of the present invention (e.g., placed in the mouth of a subject on a colorimetric test strip), then the candidate compound may be designated non-toxic and incorporated into the test assays of the present invention. The protocol in Example 1 may be followed to determine whether or not a candidate material for use in the reaction site of the test assay is toxic/non-toxic or an irritant/non-irritant.

(Spec. 44.)

Therefore, when read in light of the Specification, we interpret the term “non-toxic chromogen” in claim 1 to encompass any compound that produces a measurable color change under assay conditions, as long as the compound is capable of producing the detectable signal when used in an amount small enough to not elicit a toxic response.

9. The amount of color developing reagent on Manautou’s exemplified test strip can be as little as 0.1 milliliters of a 0.1 M solution of p-nitrophenyl-n-acetyl- $\beta$ -d-glucosaminide (Manautou, col. 3, ll. 32-34). The NTP Data Sheet does not disclose whether that amount of p-nitrophenyl-n-acetyl- $\beta$ -d-glucosaminide is toxic. The NTP Data Sheet does not state whether the amount of p-nitrophenyl-n-acetyl- $\beta$ -d-glucosaminide used in Manautou’s assay would release a toxic amount of p-nitrophenol when contacted with a subject’s tongue in the manner described in Manautou.



*PRINCIPLES OF LAW*

“To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either explicitly or inherently.” *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997). During examination, the PTO must interpret terms in a claim using “the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant’s specification.” *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

[T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . . After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

*ANALYSIS*

We agree with the Examiner that Manautou anticipates claim 1. Specifically, Manautou discloses a test for N-acetyl- $\beta$ -glucosaminidase activity in the saliva of female subjects in which a female touches her tongue with a test strip impregnated with 0.1 to 0.5 ml of 0.1 M p-nitrophenyl-n acetyl- $\beta$ -d-glucosaminide in buffer (Manautou, col. 3, ll. 20-38). After allowing the color to develop, “[t]he test strip is then compared to a standard color card that has a series of color spots similarly developed from known concentrations of the color developing compound p-nitrophenol” (*id.* at col. 3, ll. 41-53). We therefore agree with the Examiner that Manautou meets

the limitations in claim 1 of (a) providing “an assay test” that has a reaction site that produces a detectable signal in the presence of the analyte, (b) placing the reaction site into a subject’s mouth in a manner that causes saliva from the subject to be contacted with the reaction site, and (c) detecting the presence or absence of the detectable signal in the reaction site.

A preponderance of the evidence also supports the Examiner’s finding that Manautou’s assay uses p-nitrophenol in a non-toxic amount. Manautou does not disclose that the 0.1 to 0.5 ml of 0.1 M p-nitrophenyl-n-acetyl- $\beta$ -d-glucosaminide impregnated onto the test strip is in any way toxic to the subjects tested by the assay (*see, e.g.* Manautou, col. 3, ll. 20-47; *also* col. 4, ll. 38-50).

As stated in *In re Best*, 562 F.2d 1252, 1255 (CCPA 1977) (quoting *In re Swinehart*, 439 F.2d 210, 212-13 (CCPA 1971):

[W]here the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

The NTP Data Sheet submitted by Appellants discloses that serious conditions requiring prompt medical attention can arise from contacting, inhaling, or ingesting p-nitrophenol (App. Br. Appendix B at 3-5). However, that document simply does not disclose the amount of p-nitrophenol that produces those conditions. Nor does the NTP Data Sheet discuss whether, or the extent to which, the relatively small amount of p-nitrophenyl-n-acetyl- $\beta$ -d-glucosaminide impregnated onto Manautou’s test

strip would release enough p-nitrophenol to elicit any of the toxic effects listed in that document.

When the term “non-toxic chromogen” in claim 1 is given its broadest reasonable interpretation consistent with the Specification, it encompasses any compound that produces a measurable color change under assay conditions, as long as the compound is capable of producing the detectable signal when used in an amount small enough to not elicit a toxic response. It is simply not clear from the NTP Data Sheet that the relatively small amount of p-nitrophenyl-n-acetyl- $\beta$ -d-glucosaminide impregnated onto Manautou’s test strip would release enough p-nitrophenol when contacted with saliva to elicit any of the toxic effects listed in that document (*see id.* at 3-5).

We agree with Appellants that, as a general principle, p-nitrophenol is a toxic substance. However, under our claim interpretation, such compound could be used in an oral assay as long as the amount of it was not toxic to the individual. The Examiner has reasonable basis for believing that the amount of p-nitrophenyl-n-acetyl- $\beta$ -d-glucosaminide administered by Manautou would not generate toxic amounts of p-nitrophenol since it was administered to 40 patients (see FF 5) without reporting any deleterious effects and such amounts are far less than the LD50.

Appellants contend that the Examiner’s reliance on Manautou’s oral testing as evidence of the color developing agent’s non-toxicity was procedurally improper, given the fact that Appellants had submitted evidence supporting their assertion that p-nitrophenol was toxic (App. Br. 13-15). Appellants further contend that the Examiner committed factual error by “simply speculat[ing] that the p-nitrophenol taught by Manautou *et*

*al.* is ‘*apparently* in small enough amounts to be assumed safe and non-toxic’” (App. Br. 16 (quoting Final Rejection 6) (emphasis by Appellants).)

We are not persuaded by these arguments. As discussed above, we agree with the Examiner that, based on the current record, a preponderance of the evidence supports the Examiner’s conclusion that the amount of p-nitrophenyl-n-acetyl- $\beta$ -d-glucosaminide impregnated onto Manautou’s test strip would not release p-nitrophenol in a toxic amount.

Appellants argue that

p-nitrophenol is highly toxic even at very low levels, as indicated by an array of evidence provided previously and available from numerous public sources. For example, according to the U.S. Department of Health and Human Services, the oral *lethal* dose of p-nitrophenol in adult rats is approximately five thousands of an ounce. U.S. Department of Health and Human Services, Registry of Toxic Effects of Chemical Substances, National Toxicology Information Program, National Library of Medicine, 1993 (data also provided in the NTP Chemical Repository Data Sheet cited above).

(App. Br. 16)

We are not persuaded by this argument. While Appellants refer to an “array of evidence” supporting their contention that Manautou’s assay uses a toxic amount of p-nitrophenol, the only supportive document advanced by Appellants in this appeal is the NTP Chemical Repository Data Sheet.

Appellants argue that, “as the entire history of modern medicine illustrates, the mere fact that a product for oral use is disclosed in a reference is no guarantee that the product is safe or useful” (App. Br. 16).

We are not persuaded by this argument. For the reasons discussed above, we do not agree with Appellants that the evidence currently of record demonstrates that the amount of p-nitrophenyl-n-acetyl- $\beta$ -d-glucosaminide impregnated onto Manautou's test strip would result in a toxic amount of p-nitrophenol. Rather, because Manautou's test strip is impregnated with the color developing compound in an amount several orders of magnitude smaller than the lethal dose of p-nitrophenol, and because the evidence of record does not show that such a small amount would have any other toxic effects when used as described in the reference, we agree with the Examiner that a preponderance of the evidence supports the finding that Manautou's chromogen is not present in a toxic amount.

Appellants argue that the Examiner's calculation on page 6 of the Answer, purporting to show that the amount of p-nitrophenol used in Manautou's assay is significantly less than five thousandths of an ounce, is procedurally improper (Reply Br. 1-4). Specifically, Appellants argue that the Examiner's raising this issue for the first time in the Answer precludes Appellants "from gathering or providing contrary evidence within a reasonable time period and . . . preclude[s Appellants] from presenting amendments or addressing reasons for patentability that could have readily been made during prosecution on the merits if the Examiner had originally introduced the different basis for the rejection" (*id.* at 4). Appellants list eight specific actions that the Examiner's calculations have prevented them from taking, and urge that "[t]he proper course of action is for the claims to be passed to allowance or for the Office to issue a new non-final office action whereby the Examiner raises the above arguments and alleged

evidence in a context where Applicant is afforded the proper ability to respond” (*id.*).

We are not persuaded by this argument. Our review of the record indicates that Appellants raised the issue that the oral lethal dose of p-nitrophenol in rats was five thousandths of an ounce for the first time in the Appeal Brief (App. Br. 16). Thus, faced with this argument for the first time, the Examiner’s response was to calculate whether the amount used in Manautou was close to the lethal range (Ans. 6).

We do not agree with Appellants that the Examiner’s response to a new point of argument constitutes a new ground of rejection warranting reopening prosecution, even if the Examiner cites a portion of the reference that was not previously referred to. *See In re Meinhardt*, 392 F.2d 273, 280 (CCPA 1968) (“Assuming *arguendo* that the board relied upon a portion of the [cited reference] ignored by the examiner, this could not constitute a new ground of rejection . . . . [I]t is proper for the court and necessarily, the board, to consider everything that a reference discloses.” (citing *In re Azorlosa*, 241 F.2d 939 (CCPA 1957))).

Also, we see nothing that precluded Appellants from responding to the calculations by pointing out in the Reply Brief that the Examiner was incorrect. Nor do we see any rule or circumstance in the record that precluded Appellants from performing any of items (3) to (8) on page 4 of the Reply Brief, after Manautou was first cited by the Examiner in the Non-Final Rejection of December 4, 2002.

In summary, we agree with the Examiner that a preponderance of the evidence shows that Manautou’s assay uses p-nitrophenol in a non-toxic

amount. We therefore also agree with the Examiner that Manautou meets all of the limitations of claim 1. Thus, we affirm the Examiner's anticipation rejection of claim 1.

Applicable at the time Appellants' Appeal Brief was filed, 37 C.F.R. § 1.192(c)(7) states

For each ground of rejection which appellant contests and which applies to a group of two or more claims, the Board shall select a single claim from the group and shall decide the appeal as to the ground of rejection on the basis of that claim alone unless a statement is included that the claims of the group do not stand or fall together and, in the argument under paragraph (c)(8) of this section, appellant explains why the claims of the group are believed to be separately patentable. Merely pointing out what the claims cover is not an argument as to why the claims are separately patentable.

Appellants argue that "[e]ach claim stands alone. Each claim has separate limitations and must be considered independently" (App. Br. 5). With respect to claims 2-4 and 11, Appellants present separate statements that each of those claims is different from claim 1 because each has limitations beyond those present in claim 1, and also urge that "the cited prior art" does not disclose those limitations (*id.* at 5, 6, and 8).

However, contrary to the requirement in 37 C.F.R. § 1.192(c)(7), Appellants do not explain why Manautou does not meet the limitations in claims 2-4 and 11. Rather, Appellants' argument is tantamount to merely restating the limitations in the claim. *See* 37 C.F.R. § 1.192(c)(7) ("Merely pointing out what the claims cover is not an argument as to why the claims are separately patentable.") Claims 2-4 and 11 therefore fall with claim 1.

OBVIOUSNESS -- CLAIMS 5, 6, 8-15, and 18-27

Claims 5, 6, 8-15, and 18-27 stand rejected as obvious in view of Manautou and Bogema (Ans. 3-5). Claim 6 is representative of the rejected claims, and recites “[t]he method of Claim 1, wherein said reaction site comprises an antibody, wherein said antibody binds to said analyte.”

Conceding that Manautou differs from claim 6 “by not specifically pointing out that the reaction site comprise[s] an antibody,” the Examiner contends that one of ordinary skill would have considered it obvious to “incorporate an antibody as taught by . . . Bogema and utilize it in the reaction site of the test strip as taught by Manautou et al to specifically bind the analyte being detected in the saliva” (Ans. 3-4).

Appellants do not dispute the Examiner’s conclusion regarding the use of Bogema’s antibody as a means of detecting analyte in Manautou’s assay. Instead, Appellants contend that, because “none of the prior art cited by the Examiner, including the Bogema reference, teaches the use of a non-toxic chromogen for oral testing[,] . . . there is no teaching of all of the claim limitations of the presently claimed invention in the cited art, alone or in combination” (App. Br. 18). Therefore, Appellants argue, “there can also be no reasonable expectation of success in combining the cited references to achieve the presently claimed invention, since an essential element is absent” (*id.*). Appellants also contend that “the wholesale lack of a teaching of the use of a non-toxic chromogen for oral testing in the prior art is further evidence of the nonobvious nature of the presently claimed invention” (*id.* at 19).



We are not persuaded by these arguments. Because claim 6 depends from claim 1, the method recited in claim 6 is also limited to one that uses a non-toxic chromogen. As discussed above, we agree with the Examiner that Manautou meets claim 1's limitation requiring the use of a non-toxic chromogen. Manautou therefore also meets that limitation in claim 6.

Therefore, because Manautou meets the limitation in claim 6 requiring the method to use a non-toxic chromogen, and because we do not see, nor do Appellants point to, anything undermining the Examiner's conclusion that one of ordinary skill would have considered it obvious to use Bogema's antibody in Manautou's oral testing methods, we affirm the Examiner's rejection of claim 6. Appellants do not present any separate arguments regarding any of the claims subject to this ground of rejection (*see* App. Br. 18-19). Claims 5, 8-15, and 18-27 therefore fall with claim 6. 37 C.F.R. § 1.192(c)(7).

#### OBVIOUSNESS -- CLAIM 7

Claim 7 stands rejected as obvious in view of Manautou and Kindler (Ans. 5). Claim 7 recites "[t]he method of Claim 1, wherein said reaction site comprises a biosensor."

Conceding that Manautou differs from claim 7 "in not teaching the use of a biosensor," the Examiner cites Kindler as disclosing "an electrochemical immunosensor (biosensor) which uses electrical signals to measure binding events" (Ans. 5). The Examiner contends that one of ordinary skill would have considered it obvious "to modify the teachings of Manautou et al to include the use of a biosensor as taught by . . . Kindler to

not only detect the analyte in a sample, but to also measure quantities of the binding events” (*id.* (citing Kindler, col. 3, ll. 30-40)).

Appellants do not dispute the Examiner’s conclusion regarding the use of Kindler’s biosensor as a means of detecting analyte in Manautou’s assay. Instead, Appellants contend that, because neither Manautou nor Kindler “teaches the use of a non-toxic chromogen for oral testing [,] . . . there is no teaching of all of the claim limitations of the presently claimed invention in the cited art, alone or in combination. As such, there can also be no reasonable expectation of success in combining the cited references to achieve the presently claimed invention, since an essential element is absent” (App. Br. 19). Appellants also urge, again, that “the absence of a teaching of the use of a non-toxic chromogen for oral testing in the prior art is further evidence of the nonobvious nature of the presently claimed invention” (*id.*).

These arguments have been addressed above. Because claim 7 depends from claim 1, the method recited in claim 7 is also limited to one that uses a non-toxic chromogen. As discussed above, we agree with the Examiner that Manautou meets claim 1’s limitation requiring the use of a non-toxic chromogen. Manautou therefore also meets that limitation in claim 7.

Because Manautou meets the limitation in claim 7 requiring the method to use a non-toxic chromogen, and because Appellants do not point to, nor do we see, anything undermining the Examiner’s conclusion that one of ordinary skill would have considered it obvious to use Kindler’s

electrochemical immunosensor in Manautou's oral testing methods, we affirm the Examiner's rejection of claim 7.

#### SUMMARY

We affirm the Examiner's rejection of claims 1-4 and 11 under 35 U.S.C. § 102(b) as anticipated by Manautou.

We affirm the Examiner's rejection of claims 5, 6, 8-15, and 18-27 under 35 U.S.C. § 103(a) as obvious in view of Manautou and Bogema.

We affirm the Examiner's rejection of claim 7 under 35 U.S.C. § 103(a) as obvious in view of Manautou and Kindler.

#### TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)

#### AFFIRMED

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